

WE CLAIM:

- 1 1. A pharmaceutical composition comprising sertraline or a pharmaceutically
2 acceptable salt thereof and water, wherein the water comprises greater than about 10% w/w
3 to about 40% w/w of the composition.
- 1 2. The composition according to claim 1, wherein the water comprises from greater
2 than about 10% w/w to about 25% w/w of the composition.
- 1 3. The composition according to claim 2, wherein the water comprises from greater
2 than about 10% w/w to about 15% w/w of the composition.
- 1 4. The composition according to claim 2, wherein the water comprises between about
2 10.5% w/w and 12% w/w of the composition.
- 1 5. The composition according to claim 1, wherein the composition further comprises
2 one or more non-aqueous vehicles, preservatives and flavouring agents.
- 1 6. The composition according to claim 1, wherein the pharmaceutically acceptable
2 salt comprises sertraline hydrochloride.
- 1 7. The composition according to claim 1, wherein the sertraline or pharmaceutically
2 acceptable salt thereof is present in an amount of about 0.1 mg/ml to about 70 mg/ml.
- 1 8. The composition according to claim 1, wherein the sertraline or pharmaceutically
2 acceptable salt thereof is present in an amount of about 15 mg/ml to about 30 mg/ml.
- 1 9. The composition according to claim 5, wherein the non-aqueous vehicle comprises
2 one or more of ethanol, glycerine, propylene glycol or mixtures thereof.
- 1 10. The composition according to claim 9, wherein the non-aqueous vehicle comprises
2 a mixture of ethanol and glycerine.
- 1 11. The composition according to claim 5, wherein the preservative comprises one or
2 more of butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid,
3 ascorbyl palmitate, sodium metabisulfite, sodium bisulfite, sodium thiosulfate, sodium
4 hydroxide, cystiene, ethylenediamine tetraacetic acid or its salts, citric acid,
5 triethanolamine, thioglycerol, methyl paraben or propyl paraben.

- 1 12. The composition according to claim 11, wherein the preservative comprises
2 butylated hydroxytoluene.
- 1 13. The composition according to claim 5, wherein the flavouring agent comprises one
2 or more of menthol, peppermint, spearmint, citrus, strawberry, raspberry, flavour
3 blackcurrant, orange and grape fruit flavours, aspartame, saccharin sodium or mixtures
4 thereof.
- 1 14. The composition according to claim 1, wherein the composition is in the form of
2 an oral liquid concentrate.
- 1 15. The composition according to claim 1, wherein at least a portion of the water in the
2 composition is added and is not from the sertraline and/or excipients.
- 1 16. The composition according to claim 1, wherein the composition is free of
2 polyethylene glycol.
- 1 17. A process for the preparation of an orally administered liquid pharmaceutical
2 composition, the process comprising:
3 dissolving sertraline or a pharmaceutically acceptable salt thereof in one or more
4 non-aqueous vehicles to form a solution; and
5 adding water to the solution.
- 1 18. The process according to claim 17, further comprising:
2 filtering the solution to which water has been added; and
3 filling the filtered solution into a suitable container.
- 1 19. The process according to claim 17, wherein the water comprises from greater than
2 about 10% w/w to about 25% w/w of the composition.
- 1 20. The process according to claim 17, wherein the water comprises from 10% w/w to
2 about 15% w/w of the composition.
- 1 21. The process according to claim 17, wherein the water comprises between about
2 10.5% w/w and 12% w/w of the composition.
- 1 22. The process according to claim 17, wherein the pharmaceutically acceptable salt
2 thereof comprises sertraline hydrochloride.

- 1 23. The process according to claim 22, wherein the sertraline hydrochloride comprises
2 an amount of about 0.1 mg/ml to about 70 mg/ml.
- 1 24. The process according to claim 23, wherein sertraline hydrochloride comprises an
2 amount of about 15 mg/ml to about 30 mg/ml.
- 1 25. The process according to claim 17, wherein the non-aqueous vehicle comprises
2 one or more of ethanol, glycerine, propylene glycol or mixture thereof.
- 1 26. The process according to claim 17, further comprising adding one or both of a
2 preservative and a flavouring agent.
- 1 27. The process according to claim 29, wherein the preservative comprises one or
2 more of butylated hydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid,
3 ascorbyl palmitate, sodium metabisulfite, sodium bisulfite, sodium thiosulfate, sodium
4 hydroxide, cystiene, ethylenediamine tetraacetic acid or its salts, citric acid,
5 triethanolamine, thioglycerol, methyl paraben, propyl paraben or mixtures thereof.
- 1 28. A method of treating one or more of depression, panic disorder, post-traumatic
2 stress disorder, and obsessive compulsive disorder in a patient in need thereof, the method
3 comprising administering a pharmaceutical composition comprising sertraline or a
4 pharmaceutically acceptable salt and water, wherein the water is at a concentration of
5 greater than about 10% w/w to about 40% w/w of the composition.
- 1 29. The method according to claim 28, further comprising diluting the pharmaceutical
2 composition in an aqueous vehicle prior to dosing.
- 1 30. The method according to claim 29, wherein the aqueous vehicle comprises one or
2 more of water, orange juice, ginger ale, lemon lime soda, lemonade, cranberry juice,
3 grapefruit juice, tomato juice, pineapple juice or prune juice.